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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/482,283	06/07/95	THOMPSON R	04189.0083-0

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EXAMINER	
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ART UNIT	PAPER NUMBER
1812	

DATE MAILED: 01/30/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/482,283	Applicant(s) Thompson et al.
	Examiner Claire M. Kaufman	Group Art Unit 1812

☒ Responsive to communication(s) filed on *Nov 6, 1997*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-36* is/are pending in the application.

Of the above, claim(s) *1-21 and 26-36* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *22-25* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-36* are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☒ The drawing(s) filed on *Jun 7, 1995* is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

1. The amendment filed 1/30/97 has been entered.

Election/Restriction

2. Applicant's election of Group V in Paper No. 13 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. This application contains claims 1-21 and 26-36 are drawn to an invention non-elected with traverse in Paper No. 13. A complete response to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) MPEP § 821.01.

Drawings

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: In Figure 6 and Figure 7, the chromatographic peaks are given number 1-18 and 1-7, respectively, but these reference numbers are not mentioned in the description. Correction is required.

5. There is no description of Figures 20-64, added by amendment in paper #10, in the specification, particularly in the Brief Description of the Drawings. Correction is required.

6. The drawings are objected to because in Figure 4A, the text is upside down. Correction is required.

7. Figures 4, 13, 15, 25, 27-30, 40, 58, 63, and 64 of the instant application are presented on multiple separate panels. 37 C.F.R. § 1.84 (u)(1) states that when partial views of a drawing which are intended to form one complete view, whether contained on one or several sheets, must

be identified by the same number followed by a capital letter. The panels of Figures 29, 40, and 58, must be identified by the same number followed by a capital letter. The two panels labelled Figures 29-1 and 29-2, should be renumbered 29A and 29B. Also, for example, the three sheets of "Figure 40" should be renumbered "Figures 40A, 40B, and 40C". Applicant is reminded that once the drawings are changed to meet the separate numbering requirement of 37 C.F.R. § 1.84 (u)(1), Applicant is required to change the Brief Description of the Drawings and the rest of the specification accordingly (see p. 42, line 20; p. 17, line 8; p. 18, line 17; and p. 18, line 24). If, for example, Figure 4 is divided into Figures 4A and 4B, then the Brief Description and all references to this figure in the specification must refer to Figures 4A and/or 4B. While all drawings except 29, 40, and 58 are correctly numbered, *e.g.*, Figure 4A, Figure 4B, the description of the drawings does does not correspond.

Oath/Declaration

8. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed alterations have been made to the oath or declaration. See 37 CFR 1.52(c) and 1.57).

The Residence and Country of Citizenship of inventor R.C. Thompson have been altered without initialing.

Specification

9. The disclosure is objected to because of the following informalities: on page 10, line 1, "555,274" is incomplete and should be replaced with --07/555,274--; on p. 70, line 15, "SYNERGEN\PEGYLATION\CIP.DOC" should be deleted.

Appropriate correction is required.

Double Patenting

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claim 22 are rejected under the judicially created doctrine of double patenting over claim 1 in view of 4 of prior U.S. Patent No. 5,075,222, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The nucleic acid of claim 22 encodes an IL-1 inhibitor which comprises the amino acid sequence listed in that claim. This is the same sequence encoded by nucleotides 99-554 listed in claim 4 of the patent which encodes a functional IL-1 inhibitor.

11. Claims 23-25 are rejected under the judicially created doctrine of double patenting over claims 11 and 17 of U. S. Patent No. 5, 075,222, since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows:. The DNA of the current application and patent comprises a sequence encoding the polypeptide listed in claim 22 of the current application (see claims 1 and 4 of patent). Note that because the claims use the open language "comprising", more than the element specifically recited is encompassed. Additionally, claim 23 of the current application is a host cell containing DNA comprising the sequence defined in claim 22, so a host cell containing a DNA molecule which is a vector into which the encoding sequence of claim 22 has been subcloned is encompassed by claim 23 of the current application and by claim 11 of the patent. Similarly, the process of producing an IL-1 inhibitor polypeptide in the application and patent encompass the same matter. In the current application, claim 24 comprises expressing the DNA contained in the host cell of claim 23 and, then in claim 25, harvesting the polypeptide produced. In the patent, the method of production in claim 17 comprises expressing the IL-1 inhibitor encoded by DNA in a host cell (see claim 11 of patent) and harvesting the IL-1 inhibitor. Note that because claim 24 uses the language comprising, it is encompassed by claim 17 of the patent because it is permissible to have more steps than those recited in the current claim.

12. Claims 24 and 25 are rejected under the judicially created doctrine of double patenting over claim 1 of U. S. Patent No. 5,453, 490 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

wd/T.D.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: The current application claims a method comprising of producing an IL-1 inhibitor (IL-1i) polypeptide by expressing in a host cell nucleic acid which encodes an IL-1 inhibitor (claim 24) and harvesting the IL-1i polypeptide (claim 25). The patented claim is also a method of producing an IL-1i polypeptide by growing *E. coli* host cells containing DNA which encodes an

IL-1i, which is the same as that of claim 22 of the current application (see col. 1, lines 25-34, of patent which refers to a parent patented application US 5,075,222 of the current application which teaches the DNA encoding the IL-1i; see sections 10 and 11 above), and harvesting the polypeptide by cell lysis and ion exchange.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 101

13. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claim 22-23 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. DNA is naturally occurring (p. 10, lines 15-24 of specification) and is not claimed as purified and/or isolated. Additionally, Eisenberg et al. (V) showed that human monocytes contain DNA comprising the DNA of claim 22, so that the host cell of claim 23 also occurs naturally. It is noted that the term "recombinant" as used in claim 23 does not distinguish the claimed host cell from a naturally occurring cell containing the DNA because Watson et al. (W, p. 313) teach that "All DNA is recombinant DNA." Therefore, the claims do not show the hand of man involved in the invention and, as a result, are unpatentable. See MPEP § 706.03(a) and 2105.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14. Claims 22-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Hannum et al. (U).

Hannum et al. teach a polypeptide produced by human monocytes and the harvesting of this polypeptide (paragraph beginning p. 336, bottom of col. 1; and legend of Fig. 1). This polypeptide was partially sequenced as fragments, and these five fragments containing a total of 95 amino acids (Fig. 4) were 100% identitical to fragments of the polypeptide shown in claim 22 of the current application (which has 152 amino acids total). It is stated that the residues sequenced represent about 60% of the protein (p. 338, col. 2, third ¶; 95/152=62.5%). Additionally, the polypeptide was shown to be an interleukin-1 (IL-1) inhibitor (p. 339, col. 2, through p. 340, first ¶). For these reasons it appears, absent evidence to the contrary, that the polypeptide isolated by Hannum et al. is that disclosed in claim 22 of the current application and; therefore, the human monocytes described, in order to be able to express the polypeptide, must contain a nucleic acid encoding the polypeptide. The non-isolated nucleic acid of claim 22 then is the same as the nucleic acid contained in the human monocyte host cells, which produce the IL-1 inhibitor polypeptide by expressing the encoding DNA. Additionally, Hannum et al. teach isolated cloned DNA from human monocytes that appears to encode the same IL-1 inhibitor polypeptide that was purified. This DNA was expressed in *E. coli*. host cells and the encoded protein was harvested (p. 339, col. 1, second ¶).

15. Claims 22-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Eisenberg et al. (V).

Eisenberg et al. teach cDNA encoding the polypeptide shown in claim 22 of the current application (Fig. 2c). Also taught is isolated mRNA encoding the IL-1 inhibitor polypeptide (Fig. 3, arrow). The cDNA was inserted either into a non-mammalian expression vector and subsequently expressed in *E. coli* host cells followed by harvesting by extraction (paragraph beginning p. 343, end of col. 2) or into a mammalian expression vector, expressed in COS host cells, and harvested with the culture medium (p. 345, col. 1, first full ¶).

16. Claims 22-25 are rejected under 35 U.S.C. 102(a) as being anticipated by Hannum et al. (N).

Hannum et al. teach cDNA encoding a polypeptide comprising the amino acid sequence shown in claim 22 of the current application (p. 28, lines 1-35, and Fig. 14). The encoding nucleic acid was isolated from monocytes (*i.e.,* a host cell; Examples 5-6). Additionally, monocyte cells containing the nucleic acid were used to express the encoded polypeptide, an IL-1 inhibitor. Following this, the polypeptide was harvested with the cell culture (p. 16, lines 7-16 and 31-48).

17. Applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. 102(a). *In re Katz*, 215 USPQ 14 (CCPA 1982)(discussed below). Therefore, where the applicant is one of the co - authors of a publication cited against his or her application, the publication may be removed as a reference by the filing of affidavits made out by the other authors establishing that the relevant portions of the publication originated with, or were obtained from, applicant. Such affidavits are called disclaiming affidavits. *Ex parte Hirschler*, 110 USPQ 384 (Bd. App. 1952). The rejection can also be overcome by submission of a specific declaration by the applicant establishing that the article is describing

applicant's own work, *In re Katz* , 215 USPQ 14 (CCPA 1982). However, if there is evidence that the co - author has refused to disclaim inventorship and believes himself or herself to be an inventor, applicant's affidavit will not be enough to establish that applicant is the sole inventor and the rejection will stand. *Ex parte Kroger* , 219 USPQ 370 (Bd. Pat. App. & Int. 1982) (discussed below). It is also possible to overcome the rejection by adding the co - authors as inventors to the application if the requirements of 35 U.S.C. 116, third paragraph are met. *In re Searles,* 164 USPQ 623 (CCPA 1970).

18. Claims 24 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by Hageman et al. (B).

Hageman et al. teach in claim 1 a method of producing an IL-1i polypeptide by growing *E. coli* host cells containing DNA encoding an IL-1i, which is the polypeptide same as that of claim 22 of the current application (see col. 1, lines 25-34, of patent which refers to a parent patented application US 5,075,222 of the current application), and harvesting the polypeptide by cell lysis and ion exchange.

Prior Art

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Watson et al. (W) teach that "All DNA is recombinant DNA." Liao et al. (X) and Rosenstreich et al. (X) describe an IL-1 inhibitor isolated from urine.

Conclusion

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Friday from 8:00AM to 4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached at (703) 308-2957.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. NOTE: If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[stephen.walsh@uspto.gov]**.

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

cmk
January 28, 1998

Stephen Walsh
STEPHEN WALSH
SUPERVISORY PATENT EXAMINER
GROUP 1800